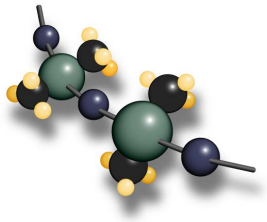

Tacky Gels for Healthcare Applications

Silicone tacky gels are ideal for processing into sheets or pads for various topical applications requiring a temporary adhesive. Some key examples include:

- Wound care
- Scar management therapies
- Transdermal therapeutic systems
- Face masks
- Ostomy and incontinence care products

Silicone gels have a history of biocompatibility, are non-allergenic, and offer superior breathability. In addition, dimethyl silicone tacky gels provide the best moisture permeability on the market, demonstrating Water Vapor Transmission Rates (WVTR) values of up to 68 gm/m^2/day.

The advantages of using a silicone gel system are:

- Solvent-free
- Modifiable tack
- Varying viscosities
- Adjustable cure profiles
- Cohesive Strength

	NuSil Test Method	MED-6342	MED-6345	MED-6350
Appearance	TM002	Translucent	Translucent	Translucent
Mixed viscosity	TM001	8,000cP	12,750 cP	27,000 cP
Worktime, time to double initial viscosity	TM001	10 hours	30 minutes	2 hours
Cure Condition		45 min @135 °C	3 hrs @ 60°C	30 min @100°C
Penetration*	TM011	1.2 mm	5.2 mm	1.8 mm
Surface Tack	TM103	11 psi	6 psi	5 psi
Cohesive Strength Cure		60 min @ 150°C	60 min @150°C	60 min @150°C
Final Elastic Modulus, G', PA	TM124	6,800	620	1,300
Final Tanδ	TM124	0.2	0.7	0.6
Surface Tack	TM103	11 psi	5.5 psi	4.5 psi

Cure time may have an affect on both surface tack and cohesive strength properties.
*LabLine Penetrometer. ¼"/19.5g, 5sec.

About NuSil Technology

NuSil Technology is a cutting edge global formulator and manufacturer of silicone compounds for the healthcare industries with 30 years of experience. Developing novel silicone systems, NuSil offers a complete line of customizable adhesives, elastomers, fluids, and gels. We meet the demands of new and innovative technologies by building on our experience and expanding our products and services to offer exclusive silicone solutions specifically designed for drug delivery and combination medical device products.

For more information, please visit:
www.silicone-polymers.com

Tacky Gels for Healthcare Applications

NuSil Technology measures surface tack via ASTM D429-Method D, which applies a 1 lb weight onto the cured gel for 30 seconds. The amount of force needed to remove the weight from the gel results in the surface tack value - the higher the value, the tackier the gel. Cohesive strength of the gel is measured by determining the rheological properties in relation to elastomeric properties. The Final Tan Delta (Tanδ) paired with the Final Elastic Modulus (G') defines the toughness of the gel. In the chart below MED-6342 has the best cohesive strength and is the toughest gel.

Custom gels can be developed to provide an optimized cure profile, viscosity, work-time, tack, cohesive strength, and water vapor transmission rate.

The MED-6342, MED-6345, and MED-6350 are all supported by the following confirmatory biological testing:

Test	Standard/ Method	Test Results
Cytotoxicity Study Using The ISO Elution Method (1X MEM Extract)	ISO 10993-5 USP <87>	A-Noncytotoxic B-Noncytotoxic C-Noncytotoxic
In Vitro Hemolysis Study (Modified ASTM -Extraction Method)	ISO 10993-4	A-Nonhemolytic
USP and ISO Systemic Toxicity Study Extract*	ISO 10993-11 USP <88>	A-Nontoxic
ISO Intracutaneous Study Extract*	ISO 10993-10 USP <88>	A-Nonirritant
ISO Muscle Implantation Study 1 Week*	ISO 10993-6 USP <88>	A-Nonirritant
Genotoxicity: Bacterial Reverse Mutation Study (DMSO and Saline Extracts)	ISO 10993-3	A-Nonmutagenic
USP Pyrogen Study Material Mediated	ISO 10993-11 USP <151>	A-Nonpyrogenic
ISO Maximization Sensitization Study Extract	ISO 10993-10	A-Nonsensitization
Mammalian Mutagenesis Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' "	----------	----------
Cytogenic Damage Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' "	----------	----------

* Product meets USP Class VI test requirements.

Test Article Conditioning

Sample	Condition
A	Per NuSil Technology Product Specification
B	Condition A + Hot Air Oven 12 Hours @ 200ºC
C	Condition A + Autoclave 2 Hours @ 15 psi

These are restricted materials and may be considered for use in short-term implant applications (29 days or less) or external applications. It is the responsibility of the device manufacturer to determine the safety and efficacy of the device and the materials used in that device. Master Files (MAF's) have either been filed, or will be filed with FDA. Please contact your Polymer Sytems Technology technical representative for additional details.

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